

REMARKS

I. Examiner Interview

Applicant thanks the Examiner for holding an interview with its representatives on November 19, 2008. The results of the interview are reflected in the amendments and remarks herein.

Examiner Theodore Stigell held an interview with Elizabeth Burke and Tyler Akagi, representatives of Applicant, to discuss the claim rejections in the Office Action dated April 17, 2008, and Applicant's Reply to Office Action dated August 11, 2008. At the interview, Applicant's representatives explained the operation of an embodiment of the claimed invention. Applicant acknowledges that, as reflected by the Office Action dated November 28, 2008, the Examiner chose to maintain some of his rejections despite the interview. The maintained rejections are addressed within this Reply.

II. Status of the Application

Claims 9-10 and 12-30 are pending in this application, with claims 9, 12, 14-15, 17-18, 20-21, and 23 being independent.

In the Office Action dated November 28, 2008, ("Office Action"), the Examiner rejected claims 9-10 and 12-29 under 35 U.S.C. § 112 ¶ 2, as allegedly being indefinite, and rejected claims 14, 17, 20, 23, and 26-29 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 02/076535 ("DCA Design International"). Applicant gratefully acknowledges the Examiner's indication that claims 9-10, 12-13, 15-16, 18-19, and 21-22, and 24-25 contain allowable subject matter.

By this amendment, Applicant has amended claims 9, 12, 15, 18, 20, 21, 23, and 24. Applicant also has added new claim 30. The claim amendments and new claim are

supported by the originally filed specification and drawings, and no new matter has been entered. Applicant respectfully requests in light of these amendments and the remarks below that the Examiner withdraw the rejections of claims 9-10 and 12-29, and allow the pending claims to proceed to issue.

III. Rejections Under § 112 ¶ 2

The Office Action rejects claims 9-10 and 12-29 under 35 U.S.C. § 112 ¶ 2 as allegedly being indefinite. The Office Action alleges that “there seems to be some inconsistency in the claim language. . . . It is unclear if the elements belong to the drive mechanism or drug delivery device.” Office Action at 2. Applicant submits that in light of the amendments to the claims, these rejections are moot.

Claim 9, for example, recites a *drive mechanism* for a drug delivery device comprising “an epicyclic gearbox; a piston rod . . . and a drive sleeve.” Claim 15, by contrast, recites a *drug delivery device*, comprising “a drive mechanism . . . a housing . . . and a dose dial sleeve.” The remaining independent claims, as amended, present additional distinctions between a drive mechanism and a drug delivery device.

Because the claims as amended are not indefinite, Applicant respectfully requests that the Examiner remove these rejections and allow the claims.

I. Rejections Under § 102(b)

The Office Action rejects claims 14, 17, 20, 23, and 26-29 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 02/076535 to DCA Design International (“WO ’535”). Office Action at 2. The Office Action asserts that WO ’535 discloses a drug injection device comprising, *inter alia*, a drive sleeve (30, 18), dose dial means (42), and a piston (8, 10). The Office Action alleges that WO ’535 discloses elements

“that can be interpreted as a drive sleeve.” Applicant respectfully disagrees with the Office Action’s interpretation of the cited reference and the claim terms “drive sleeve” and “dose dial sleeve.”

WO '535 is directed to improvements in and relating to an injection device. The injection device disclosed in WO '535 includes a piston member 10 connected with a semi-rigid belt 18. A dose dial means 42 is used by a user to set a dose. A user may rotate the dose dial means, causing rotation of a dose setting spindle, thereby driving an outer gear 22 through a worm gear. WO '535 at 6 ¶ 2. Operation of the dose dial means 42 causes rotation of the dosing spindle 38 and an associated spline 40. WO '535 at 5 ¶ 1.

A. Independent Claim 14

Claim 14 recites a “drug injection device, comprising . . . a drive sleeve configured to engage a piston.” As defined by the specification, a drive sleeve is an “essentially tubular component of essentially circular cross-section and which is engaged with the piston rod.”

As explained more fully above, WO '535 discloses a *semi-rigid belt* 18, which is neither “essentially tubular” nor of “essentially circular cross-section.” Thus, nothing in WO '535 teaches or suggests at least a “drive sleeve” as claimed in claim 14 or as understood within the context of the specification. See MPEP § 2111.01(IV) (“An applicant is entitled to be his or her own lexicographer . . .”).

For at least the above reasons, claim 14 is patentable over WO '535. Accordingly, Applicant respectfully requests the withdrawal of this rejection and the allowance of the claim.

B. Independent Claim 17

Claim 17 recites a method of assembling a drug injection device, comprising “providing a dose dial sleeve configured to drivingly engage the epicyclic gearbox.”

As explained above, WO '535 discloses a dial dose means 42, which engages a spindle, which drives an outer gear through a worm gear. Nothing in WO '535 teaches or suggests that the dial dose means 42 is configured to *drivingly engage* the epicyclic gearbox as claimed in claim 17. Instead, the *spindle* of WO '535 transfers movement of the dial dose means 42 to the epicyclic gearbox, while the dial dose means 42 does not engage the epicyclic gearbox at all.

For at least the above reasons, claim 17 is patentable over WO '535. Accordingly, Applicant respectfully request the withdrawal of this rejection and the allowance of the claim.

C. Independent Claim 20

Claim 20, as amended, recites a method of assembling a drug injection device comprising “providing an assembly including a drive mechanism including an epicyclic gearbox and a piston rod including a non-circular cross-section and an external helical thread.” Nothing in WO '535 teaches or suggests that the piston (10, 8) includes a non-circular cross-section and an external helical thread” as claimed in claim 20.

Accordingly, Applicant respectfully requests the withdrawal of this rejection and the allowance of the claim.

D. Independent Claim 23

Claim 23, as amended, recites a method of dispensing a medicinal product, comprising “providing a drug delivery device including a drive mechanism including an

epicyclic gearbox and a piston rod including an external helical thread.” Nothing in WO '535 teaches or suggests at least that the piston (10, 8) includes an “external helical thread” as claimed in claim 23. In addition, Applicant notes that the subject matter added to claim 23 includes features formerly presented in claim 24, which the Office Action indicates included patentable subject matter.

For at least the foregoing reasons, Applicant submits that claim 23 is patentable over the cited reference. Accordingly, Applicant respectfully requests withdrawal of this rejection and allowance of the claim.

E. Remaining Dependent Claims

Each of dependent claims 10, 13, 16, 19, 22, and 24-30 depends from one of independent claims 9, 12, 14, 15, 17, 18, 20, 21, and 23. Thus, each pending dependent claim is allowable for at least the same reasons discussed above regarding the independent claims. In addition, each of these dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and, therefore, each is also separately patentable.

Accordingly, Applicant respectfully requests the allowance of the dependent claims.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicant submits that the pending claims are patentable over the reference cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.


Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: March 30, 2009

By: _____


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